DETAILED ACTION

Claim Objections

1. Claims 1, 4, and 10 are objected to because of the following informalities: The use of the term "and/or" on line 8 of claim 1, line 4 of claim 4, and line 11 of claim 10 is objected to. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the limitation "the input device" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the concentration Cdi" in line 9 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaldon et al. (US 6,284,141).

4. With respect to Claim 1, Shaldon discloses a blood treatment device comprising a dialysis filter having two chambers separated by a semi-permeable membrane 8. The first chamber is part of a dialysis circuit having a dialysis fluid inlet and an outlet, and the second chamber is part of an extracorporeal blood circuit having a blood inlet and outlet. See Figure 4. The system further comprises a sensor (10, 11, 12) connected to an computer 14, said computer 14 being capable of determine the concentration of a substance in the blood, the transfer rate of the substance (i.e. efficiency), and total quantity of the substance withdrawn by the membrane (Column 7, Lines 27-58). The analyzer unit has an admissible value range for the concentration, transfer rate (efficiency), and quantity removed, such that it is configured to inform the control unit that the device is performing properly and make appropriate changes when the value is outside the desired ranges (Column 5, Lines 23-63) (see Figure 2, for example). Shaldon, however, does not explicitly state that the system comprises both an analyzer unit *and* a control unit. The computer 14 disclosed by Shaldon is configured to receive and analyze data, and control the system based on said data. The computer, therefore, functions in the same manner that a separate analyzer and controller would function. It would have been obvious to one of ordinary skill in the art at the time of invention to separate the computer of Shaldon into a separate analyzer and controller because doing so would not change the functionality of the device. See MPEP § 2144.04.

5. With respect to Claim 2, at least one sensor (12) is provided in the dialysis fluid outlet line for determining the concentration of the substance.

6. With respect to Claim 6, the transfer rate value range extends from zero to a user-defined maximum value (i.e. "limit value").

7. With respect to Claims 7 and 8, the computer 14 controls the system such that a target value (i.e. "desired dose") of the substance is withdrawn (Column 8, Lines 1-7). A time-controlled ending can be programmed, thereby allowing the treatment to take a specific amount of time to complete.

Claims 3-5 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaldon in view of Bosetto et al. (6,793,827).

With respect to Claims 3-5 and 10-12, Shaldon discloses the system substantially as claimed, But does not specifically disclose that a second sensor is provided in the fluid inlet line for determining the substance. Bosetto discloses a dislysis system comprising a potassium sensor downstream of the dialyzer. Optionally, the system may also comprise a potassium sensor upstream of the dialyzer (Column 7, Lines 18-22), such that the difference between the potassium concentrations upstream and downstream of the dialyzer may be more accurately measured, thereby allowing the controller to accurately determine the exact amount of a substance being transferred into or out of the blood. Specifically, the use of multiple potassium sensors allows for the treatment of uremic patients by removing excess potassium from the blood (Column 1, Lines 37-53), and maintaining blood potassium concentrations at a

specific level. This method of preventing hyperkalemia and hypokalemia is well established in the art of blood treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the dialysis system of Shaldon with the upstream and downstream potassium sensors of Bosetto in order to accurately remove a specific amount of potassium from the blood, thereby preventing diseases such as hyperkalemia.

Additionally, regarding claims 10-12, Shaldon discloses a plurality of sensors, including flow rate sensors and a concentration sensor. The sensors allow the computer to reduce the blood concentration at an efficient rate (i.e. lowering the blood concentration at the maximum possible transfer rate). The computer determines the concentration and flow rate of the targeted substance (see above). Once determining these values, the computer compares the concentration to the targeted concentration value and compares the flow rate to the targeted flow rate value. Shaldon, however, does not specifically disclose a concentration sensor upstream of the dialyzer for determining the concentration upstream before the exchange. Bosetto discloses a dialyzer that has upstream and downstream potassium sensors for determining the concentration of potassium in the fluid. The controller uses the concentration readings from these sensors to determine the amount of potassium removed from the blood via the dialyzer. Based on the readings from the sensors, the desired concentration, and the desired flow rate, the controller is capable of optimizing the system parameters to remove potassium from the blood as efficiently as possible based on a series of characteristics curves (see Figure 3) (Column 6, Lines 9-57). It would have been

obvious to one of ordinary skill in the art at the time of invention to use the system with multiple flow sensors of Shaldon with the multiple potassium sensors of Bosetto in order to allow for concentration and flow rate measurements at any point in the flow path. The addition of these sensors would increase the overall accuracy of the system, thereby, allowing the controller to remove the targeted substance as quickly as possible. By adding an upstream concentration sensor to the Shaldon device, it would be *fully capable* of performing the intended function.

With respect to Claim 13, Sheldon and Bosetto disclose the system substantially as claimed (see above). Shaldon, however, does not specifically disclose that the system comprises an input device. Bosetto further discloses an input device 32 for inputting reference values into the computer. These reference values are then used in calculations related to the operation of the device (column 6, Lines 9-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify device of Shaldon with the input device of Bosetto in order to give the controller more information about the characteristics of the flow paths, thereby allowing for more accurate calculations and allowing the system settings to be tweaked for each individual patient (Column 6, Lines 9-26).

With respect to Claim 9, Sheldon and Bosetto disclose the device substantially as claimed. Bosetto further disclose that the the quantity of potassium eliminated during treatment depends directly on the difference between the concentration of potassium in

the blood and the concentration of potassium in the dialysis fluid (Column 1, Lines 38-64). Therefore, it is obvious that the controller control the system such that the potassium concentrations of the dialysis fluid and blood will be equal when the process is complete, thereby preventing additional potassium removal from the blood.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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